

Applicable Drugs: Evkeeza (evinacumab-dgnb), Juxtapid (lomitapide), Leqvio (inclisiran), Nexletol (bempedoic acid), Nexlizet (bempedoic acid and ezetimibe), Praluent (alirocumab), Repatha (evolocumab)

Preferred: N/A

Non-preferred: N/A

VSI Excluded Drugs: Evkeeza (evinacumab-dgnb), Leqvio (inclisiran)

Date of Origin: 4/27/2023

Date Last Reviewed / Revised: 4/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

- I. The patient meets specific diagnosis criteria listed for the requested medication in Table 1.
- II. Documented treatment with two maximally tolerated high-intensity statins (e.g., atorvastatin 40 mg to 80 mg per day, rosuvastatin 20 mg to 40 mg per day) and ezetimibe daily for ≥ 12 weeks AND one of the following A through D:
 - A. Very high-risk Clinical ASCVD
 - i. LDL-C remains ≥ 55 mg/dL
 - B. Clinical ASCVD not meeting very high-risk criteria
 - i. LDL-C remains ≥ 70 mg/dL
 - C. Severe Primary Hypercholesterolemia (baseline LDL-C ≥ 190 mg/dL) AND i or ii:
 - i. LDL-C remains ≥ 100 mg/dL
 - ii. LDL-C remains ≥ 70 mg/dL with additional high-risk features (eg, ASCVD risk factors, FH, subclinical atherosclerosis)
 - D. 50% reduction in LDL-C has not been achieved.
- III. Documentation that patient will continue to take and is adherent to high-intensity statin therapy (e.g., atorvastatin 40 mg to 80 mg per day, rosuvastatin 20 mg to 40 mg per day) at the maximally tolerated dose.
- IV. Must be prescribed by or in consultation with a doctor of internal medicine, cardiologist, or endocrinologist.
- V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Repatha and Praluent: Concurrent use of more than one PCSK9 inhibitor
- Nexlizet: Concurrent use with simvastatin >20 mg, pravastatin >40 mg, or fibrates (other than fenofibrate), documented hypersensitivity reaction to ezetimibe, or documented history of gout, hyperuricemia, tendon rupture, tendon disorders, chronic liver disease, or abnormal liver enzymes
- Nexletol: Concurrent use with simvastatin >20 mg or pravastatin >40 mg, documented history of tendon rupture or tendon disorders, or history of chronic liver disease or abnormal liver enzymes

OTHER CRITERIA

- To be considered adherent, the patient must have a proportion of days covered of at least 75% over the previous six months
- Table 1. Medication-Specific Criteria for Hypercholesterolemia Agents

Medication	Medication-Specific Criteria	Dosing Limits
Injectable Agents		
Praluent (alirocumab)	• One of the following: ○ Clinical ASCVD or at high risk ○ FH diagnosed with genetic testing ○ LDL-C ≥ 190 mg/dL prior to statin treatment ○ Clinical ASCVD with elevated Lp(a) ≥ 50 mg/dL • Age requirement ○ Clinical ASCVD or at high risk: ≥ 18 years ○ FH: ≥ 8 years	2 pens/syringes per 28 days (75 mg/mL or 150 mg/mL)
Repatha (evolocumab)	• One of the following: ○ Clinical ASCVD or at high risk ○ FH diagnosed with genetic testing ○ LDL-C ≥ 190 mg/dL prior to statin treatment ○ Clinical ASCVD with elevated Lp(a) ≥ 50 mg/dL • Age requirement ○ Clinical ASCVD or at high risk: ≥ 18 years ○ FH: ≥ 10 years	2 pens/syringes or 1 Pushtronex system per 28 days
Leqvio (inclisiran)	• All of the following: ○ Clinically significant treatment failure or contraindication to Repatha and Praluent ○ Not used in combination with a PCSK9 inhibitor • Age requirement ○ ≥ 18 years	284 mg as a single injection, again at 3 months, and then every 6

		months thereafter
Evkeeza (evinacumab)	- All of the following: - HoFH - Pre-treatment LDL-C ≥ 400 mg/dL - History of xanthomas before 10 years of age or clinically diagnosed FH in both parents - Clinically significant treatment failure or contraindication to Praluent and Repatha - Age requirement ≥ 5 years	15 mg/kg IV per 28 days
Oral Agents		
Juxtapid (lomitapide)	- All of the following: - HoFH - Baseline ALT, AST, alkaline phosphatase, and total bilirubin - Pre-treatment LDL-C ≥ 400 mg/dL - History of xanthomas before 10 years of age or clinically diagnosed FH in both parents - Clinically significant treatment failure or contraindication to Praluent and Repatha - Not used in combination with a PCSK9 inhibitor - Age requirement ≥ 18 years	60 mg once daily (30 capsules per 30 days)
Nexletol (bempedoic acid)	- One of the following: - Clinical ASCVD or at high risk - HeFH diagnosed with genetic testing OR measured LDL-C ≥ 190 mg/dL prior to statin treatment - Age requirement ≥ 18 years	30 tablets per 30 days
Nexlizet (bempedoic acid and ezetimibe)	- One of the following: - Clinical ASCVD or at high risk - HeFH diagnosed with genetic testing OR measured LDL-C ≥ 190 mg/dL prior to statin treatment - Age requirement ≥ 18 years	30 tablets per 30 days
FH: familial hypercholesterolemia, HoFH: homozygous familial hypercholesterolemia, HeFH: heterozygous familial hypercholesterolemia, ASCVD: clinical atherosclerotic cardiovascular		

disease, LDL-C: low-density lipoprotein cholesterol, ALT: alanine transaminase, AST: aspartate aminotransferase, Lp(a): lipoprotein(a)

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Requested quantities not exceeding dosing limits listed in Table 1.

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Documentation of ONE of the following a through c is also required:
 - a. Current fasting LDL-C is below guideline-directed goal for risk category.
 - Very high-risk ASCVD: ≤ 55 mg/dL
 - Clinical ASCVD not meeting very high-risk criteria: ≤ 70 mg/dL
 - b. LDL-C reduction of ≥ 40 -50% mg/dL from baseline.
 - c. Renewal request is for PCSK9 inhibitor with documentation of clinical ASCVD and baseline elevated Lp(a) ≥ 50 mg/dL.

APPENDIX

N/A

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.